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EXAMINER

HADDAD, MAHER M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 05/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/030,735

**Applicant(s)**

ROBERTS ET AL.

**Examiner**

Maher M. Haddad

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12 and 15-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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#### DETAILED ACTION

1. Claims 1-45 are pending.
2. Applicant's election with traverse of Group I, claims 1-10 and 13-14 drawn to a peptide comprising the sequence R1-X1-X2-X3-X4-R2, and the NVRF (SEQ ID NO: 51) to correspond to X1-X2-X3-X4 and VF to correspond to R2 as the species, filed on 30/30/04, is acknowledged.

Upon reconsideration Examiner has extended the search to cover DVRF of SEQ ID NO: 54 to correspond to X1-X2-X3-X4.

Applicant's traversal is on the grounds that Group I is related to Groups II and III as a subcombination to a combination. Applicant contends that no basis for restriction according to the standards for the combination/subcombination has been presented. Similarly, Applicant argues that Group II and each of Groups IV and V, which are also related as subcombination to combination should also be withdrawn. Further, Applicant contends that Groups VI to IX and XI to XVII are methods for the use of a peptide according at least Group I and so is potentially subject to rejoinder. Similarly, Group X is a method for the use of the invention of Group II. Applicant traverses the restriction of Groups XII to XVII on the bases that claim 37 is a linking claim which links the invention of claims 38-43. Applicant points out the division of the claims based upon the disease to be treated is an assertion of each disease as representing different species. This is not found persuasive because a two-way distinctness of claims drawn to combination/subcombination must be shown that 1) the combination as claimed does not depend on the particulars of the subcombination for patentability; and 2) the subcombination can be shown to have utility either by itself or in other and different relations (MPEP 806.05(c)). With respect to the combination, "A peptide-substrate combination" of Group II, differ in scope from the combination of the "a peptide" of Group I in that the peptide of Group I, disclaim the peptides of SEQ ID NOs: 6 and 12. Furthermore, the "peptide" of Group I are capable of separate manufactured, used and sold separately for the "peptide-substrate combination" of Group II. Therefore, the "peptide" of group I has a utility without the features recited in the combination claims. Regarding Groups XII-VIII the different diseases are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Therefore the products and methods of Groups I-XVII are distinct and independent, and searches of all groups would place an undue burden upon the examiner due to the distinct and divergent subject matter of each Group. Further, a prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention.

The requirement is still deemed proper and is therefore made FINAL.

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3. A clear and obvious typographical error occurred in the restriction wherein claims 40-42 which reads the method of treating an angiogenesis-mediated disease, wherein the angiogenesis-mediated disease is a cancer of Group XVII were improperly excluded from nonelected Group XVII. Therefore claims 40-42 are drawn to a nonelected invention.
4. Claims 11-12 and 15-45 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
5. Claims 1-10 and 13-15 are under examination as they read on an a peptide comprising the sequence R1-X1-X2-X3-X4-R2 and compositions thereof, SEQ ID NOs: 51 and 54 that correspond to X1-X2-X3-X4 and VF corresponds to R2. It is noted that SEQ ID NOs: 19, 22 and 24-32 read on the elected species.
6. References A, N, O and V1, W1, X1, U2 and V2 cited on the PTO FORM 892 are the same references listed on the international preliminary examination report and will not be supplied.
7. Claim 4 is objected to because of the following informalities: Claim 4 is missing the phrase "wherein the" in the first line after claim 1. Appropriate correction is required.
8. Claim 10 is objected to under 37 CRD 1.821(d) because it lacks an amino acid sequence identifier.
9. The following is a quotation of the second paragraph of 35 U.S.C. 112.  
*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*
10. Claims 2 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
  - A. Claims 2 and 9 are indefinite for reciting "from about 4 to about 12 amino acid" in line 1. It is unclear how many amino acids constitute "about". One of skill in the art would not know if applicant meant 3 amino acid, as many as 13 amino acids, or even more.
11. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*
12. Claims 1-10 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a peptide consisting of SEQ ID NOs: 19, 22 and 24-32 or

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their full retro-inverso peptide sequence, does not reasonably provide enablement for any peptide "comprising" the sequence R1-X1-X2-X3-X4-R2 in claim 1, wherein R1 is a peptide "comprising" SEQ ID NO:13-17 in claim 3, or wherein the peptide "comprising" "at least one sequence" of SEQ ID NO:18-32 in claim 4, wherein the peptide is "partial retro-inverso peptide sequence in claim 6, that comprises "at least one D-amino acid" in claim 7, a retro-inverso synthetic peptide "comprising" the amino acid sequence in claim 8, the peptide of claim 6 "comprising" the sequence of SEQ ID NO: 25 in claim 10, or a pharmaceutical composition comprising a peptide and pharmaceutical acceptable carrier of claim 13, or a sterile composition comprising a peptide and a sterile aqueous solution of claim 14. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

The term "comprising" in claims 1, 3-4, 8, 10 and 13-14 is open ended and extend the peptides to include additional non-disclosed amino acids on either or both sides of the N-terminal or C-terminal of the sequence R1-X1-X2-X3-X4-R2, SEQ ID NOs: 13-17, 21-22, and 24-32. Further, the formula R1-X1-X2-X3-X4-R2 requires 1 to 6 amino acids at the N terminal and 1-3 amino acids at the C-terminal, however, the specification does not provide guidance on what amino acid can be used at each position. It has been well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different biological activities. Because of the lack of sufficient guidance and predictability in determining which modifications would lead to the inhibition of  $\alpha\beta 1$ /TSP1 interaction and that the relationship between the peptide and its activity was not well understood. It is recognized in the art that ligands must possess significant structural and chemical complementarity to their target receptors (Kuntz, Science, 1992, Vol. 257:1078-1082, especially page 10709, 2<sup>nd</sup> col., lines 1-4 and 9-12 under heading "Structure-Based Design) and that ligands generally bind to native states of proteins with little or no interaction with unfolded states (Miller et al, Protein Science, 1997, 6:2166-2179, especially page 2166, 2<sup>nd</sup> col., lines 18-20) and further that alterations in protein structure lead to alterations in bindings affinity proportional to the magnitude of the alteration (Miller et al, abstract, lines 2-4). Finally, Kuntz teaches that as little as 2% of compounds predicted to inhibit specific enzymatic or receptor systems actually shown inhibition in the micromolar range (page 1080, 3<sup>rd</sup> col.). It would be reasonable to conclude that alterations in peptide would lead to a large alteration in binding affinity. It would require an undue amount of experimentation for one of skill in the art to arrive at the breadth of inhibition of  $\alpha\beta 1$ /TSP1 interaction. Without sufficient guidance, the changes which can be made in the structure of the "peptide" and still provide inhibition of  $\alpha\beta 1$ /TSP1 interaction is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claim 4 recites a peptide comprising at least one of the recited sequences, however the specification fails to provide sequences that contain more than one of the sequences.

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Also, at issue is the partial retro-inverso peptide sequence which comprises at least one-D-amino acid. The specification on page 34, discloses peptide 709, which is all D amino acid. No partial retro-inverso peptide sequences has been disclosed, not at least one D-amino acid. Therefore, one skilled in the art at the time of the invention would not be able to predict which amino acid of the peptide can be D-amino acid and still provide inhibition of  $\alpha 3\beta 1$ /TSP1 interaction. Consequently the skilled artisan would not know how to make the instant invention as broadly claimed.

Further, at issue is whether or not the claimed composition would function as pharmaceutical/sterile composition. In view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the pharmaceutical composition as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed pharmaceutical composition are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed pharmaceutical composition with a reasonable expectation of success.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

13. Claims 1-10 and 13-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of a peptide consisting of SEQ ID NOs: 19, 22 and 24-32 or their full retro-inverso peptide sequence.

Applicant is not in possession of any peptide "comprising" the sequence R1-X1-X2-X3-X4-R2 in claim 1, wherein R1 is a peptide "comprising" SEQ ID NO:13-17 in claim 3, or wherein the peptide "comprising" "at least one sequence" of SEQ ID NO:18-32 in claim 4, wherein the peptide is "partial retro-inverso peptide sequence in claim 6, that comprises "at least one D-amino acid" in claim 7, a retro-inverso synthetic peptide "comprising" the amino acid sequence in claim 8, the peptide of claim 6 "comprising" the sequence of SEQ ID NO: 25 in claim 10, or a pharmaceutical composition comprising a peptide and pharmaceutical acceptable carrier of claim 13, or a sterile composition comprising a peptide and a sterile aqueous solution of claim 14.

Applicant has disclosed only SEQ ID NOs: 19, 22 and 24-32 or their full retro-inverso peptide sequence; therefore, the skilled artisan cannot envision all the contemplated amino acid sequence possibilities recited in the instant claims. Consequently, conception cannot be achieved until a

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representative description of the structural and functional properties of the claimed invention has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

*(e2) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.*

*The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).*

15. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Prater et al (J Cell Biol. 112(5):1031-40, 1991).

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Parater et al teach a 19 amino acid peptide comprising the sequence QVRI (see page 1031, Figure 8, under P.Falciparum C.S. protein in particular), wherein X1 is Q, X2 is V, X3 is R and X4 is I, wherein R1 is a peptide of 1-6 amino acids, and R2 is one amino acid. The term "comprising" in instant claim 1 is open ended. It would open up the claim to include the reference 19 amino acid sequence.

The reference teachings anticipate the claimed invention.

16. Claims 1-2, 6-9 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Miles et al (J Biol Chem. 269(49):30939-30945, 1994, of record).

Miles et al teach peptides comprising DLRL and are 14 amino acid in length (see page 30943, Tables I and II in particular), wherein X1 is D, X2 is L, X3 is R and X4 is L, wherein R1 is a peptide of 5 amino acids, and R2 is a peptide of 1-3 amino acid. Miles et al further teach a peptide that is all D-amino acid (see table II, 2<sup>nd</sup> sequence in particular). Miles et al further teach that the peptides were dissolved in 1 ml of DMS/water (1:9), and diluted to desired concentrations with PBS (see page 30940, 2<sup>nd</sup> col., under cell adhesion in particular). PBS is considered to be a pharmaceutically acceptable carrier. The term "comprising" in instant claim 1 is open ended. It would open up the claim to include the reference 14 amino acid sequence.

Claims 2 and 9 are included because the word "about" would open the claims to include the 14 amino acid sequences.

The reference teachings anticipate the claimed invention.

17. Claims 1-2, 5-9 and 13-14 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/09628.

The '628 publication teaches the a 6 amino acid peptide comprising the sequence DVRF (claimed SEQ ID NO: 54) (see page 36, line 15, published claim 10 in particular), wherein X1 is D, X2 is V, X3 is R and X4 is F, wherein R1 is one amino acid, and R2 is one amino acid. The '628 publication teaches that the peptide contain at least one D-amino acid (see published claim 1 in particular). The '628 publication further teaches a composition having the peptide **KDVRFE** (see published claim 17, page 43 in particular).

The reference teachings anticipate the claimed invention.

18. Claims 1-2, 6-9 and 13-14 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,020,312.

The '312 patent teaches the a 6 amino acid peptide comprising the sequence SLRF (see col. 39, SEQ ID NO:19, in particular), wherein X1 is S, X2 is L, X3 is R and X4 is F, wherein R1 is 2

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amino acids, and R2 is a hydroxide/amide (see col., 25, under Example XIII in particular) The '312 patent teaches that the peptide contain one or two D-amino acids (see col., 5, lines 52-54, in particular). The '312 patent further saline solutions, pharmaceutically acceptable buffers and solvents and the like may also be utilized as carriers for the peptide compositions of the invention (see col. 7, lines 65-67 in particular).

The reference teachings anticipate the claimed invention.

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

*(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.*

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

20. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prater et al in view of U.S. Patent NO. 5,770,563.

The teachings of Prater et al publication have been discussed, supra.

The claimed invention differs from the reference teachings only by the recitation of Partial and full retro-inverso peptide sequences in claim 6, at least one D-amino acid in claim 7, all amino acids are D-amino acids in 8.

The '563 patent teaches thrombospondin peptides which all D-amino acid peptide analog of a peptide from the A chain of the extracellular matrix protein laminin replicated the activity of the natural sequence to influence tumor cell adhesion and growth in vitro and in vivo (page 255-258 in particular). The '563 patent further teaches that retro-inverso peptides have been successfully applied to increase the stability and biological activity of peptide sequences for therapeutic applications. Finally, the '563 patent teaches that the peptides may be modified to include full or partial retro-inverso sequences. Use of retro-inverso peptide sequences minimizes enzymatic degradation and, therefore, extends biological half-life of the peptide moiety (see col., 25-55, in particular).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the amino acids of the peptide taught by the Prater et al full or partial retro-inverso sequences as taught by '563 patent.

One of ordinary skill in the art at the time the invention was made would have been motivated to do so because use of retro-inverso peptide sequences minimizes enzymatic degradation and, therefore, extends biological half-life of the peptide moiety as taught by the '563 patent.


From the combined teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

21. No claim is allowed.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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